REMARKS

Reconsideration and allowance in view of the amendments above and the discussions below are respectfully requested.

Claim 14 has been amended to correct a grammatical error. Claims 15 and 16 have been amended to correct an informality regarding the beginning article in dependent claims.

Claims 2, 5, 14-15, 16-17, 21, and 27 have been amended to more clearly define the claimed invention. Support for the claims as amended is found throughout the specification and claims as orginally filed. The term "biological" in claim 16 is defined in the specification as originally filed on page 20, lines 16-21.

Entry of the claims as amended is respectfully requested. Claims 2, 5, 15-17, 19, 21, 27-28 are under examination.

Claims 2, 5, 15-17, 19, 21, and 27-28 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In compliance with 37 CFR 1.808, Applicants hereby declare that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited

B

material will be irrevocably removed upon the granting of a patent.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 17 and 19 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled. This rejection is traversed in view of the following.

The monoclonal antibody 6B2-2 is specific for botulinum neurotoxin serotype A. Prior to cloning and expansion of the hybrid cells producing 6B2-2, the antibody was tested for its ability to protect against intoxication with BoNT in an *in vivo* mouse model. Please see pages 32, lines 11-30, and Table 1 on page 33. 6B2-2 protected three out of three mice against intoxication when challenged with 20 LD50 of BoNTA, and in another *in vivo* assay shown in Table 1, five out of five mice were protected against intoxication when challenged with 5 LD50 of BoNTA. Therefore, the application clearly describes a therapeutic use in the claimed monoclonal antibody and illustrates a beneficial response in a mouse model. Hence, in view of the 100% protection achieved in the mouse model, one of skill in the art would be able to make and use the claimed invention in a therapeutic context.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 2, 5, 14-17, 19, 21 and 27 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite.

B

The claims as amended are believed to be definite. Reconsideration and withdrawal of the rejection are requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made in Claims".

This application is believed to be in condition for allowance and notice to that effect is respectfully solicited.

Respectfully submitted,

By S.A. Pratt, Reg No. 39,441
Elizabeth Arwine
Reg. No. 45,867
301 619-2221

U.S. A. MRMC
Staff Judge Advocate Office
504 Scott Street
Fort Detrick, MD 21702-5012
ATTN: MCMR -JA (Elizabeth Arwine-Patent Atty)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner of Patents, Washington, D.C. 20231, on April 3, 2002.

By S.A. Pratt
Sana A. Pratt
Reg. No. 39,441

B

Version with Markings to Show Changes Made in Amended Claims

IN THE CLAIMS

2 (Amended). [A monoclonal] Monoclonal antibody [, MAb] 6B2-2, produced from hybridoma cell line having accession number ATCC PTA-969.

5 (Amended). [A] The continuous hybridoma cell line having deposit accession number ATCC PTA-969, and clones thereof [, which cell line produces monoclonal antibody to BoNT/A,].

14 (Amended). A method for detecting BoNT/A said method comprising:

(i) incubating a sample with an effective amount of at least one monoclonal antibody against BoNT/A, under conditions which allow the formation of an antibody-BoNT/A complex; and

(ii) detecting the antibody-BoNT/A complex wherein the presence or absence of the [comples] complex indicates the presence or absence of BoNT/A in the sample.

15 (Amended). [A] The method for detecting BoNT/A according to claim 14 wherein, said monoclonal antibody is [chosen from the group consisting of 4A2-2,] 6B2-2 [, and 6C2-4].

16 (Amended). [A] The method for detecting BoNT/A according to claim 15 wherein, said sample is water,

B

[biologicals] biological, [pharmaceuticals] pharmaceutical, or food products.

17 (Amended). A method of treating BoNT/A intoxication comprising administering to a patient in need of said treatment an amount of [a] monoclonal antibody [selected from the group consisting of: 4A2-2,] 6B2-2 [, and 6C2-2] sufficient to effect said treatment.

21 (Amended). A kit for detecting BoNT/A in a biological sample, said kit comprising:

(1) a container [holding at least one] having [monoclonal antibody selected from the group consisting of MAb 4A2-2,] MAb 6B2-2 [, and MAb 6C2-2]; and

(2) instructions for using the antibody for the purpose of binding to BoNT/A to form an immunological complex and detecting the formation of the immunological complex such that presence or absence of immunological complex correlates with presence or absence of BoNT/A in said sample.

27 (Amended). A method for capturing BoNT/A from a sample, said method comprising contacting said sample with [one or more] monoclonal antibody [selected from the group consisting of 4A2-4,] 6B2-2, [and 6C2-2,] and isolating the complex formed between the BoNT/A in the sample and the monoclonal antibody.

B